

Food and Drug Administration, HHS

§ 822.21

of useful data that will answer the surveillance question.

§ 822.17 How long will your review of my submission take?

We will review your submission within 60 days of receipt.

§ 822.18 How will I be notified of your decision?

We will send you a letter notifying you of our decision and identifying any action you must take.

§ 822.19 What kinds of decisions may you make?

If your plan:	Then we will send you:	And you must:
(a) Should result in the collection of useful data that will address the postmarket surveillance question	An approval order, identifying any specific requirements related to your postmarket surveillance	Conduct postmarket surveillance of your device in accordance with the approved plan
(b) Should result in the collection of useful data that will address the postmarket surveillance question after specific revisions are made or specific information is provided	An approvable letter identifying the specific revisions or information that must be submitted before your plan can be approved	Revise your postmarket surveillance submission to address the concerns in the approvable letter and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit
(c) Does not meet the requirements specified in this part	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit
(d) Is not likely to result in the collection of useful data that will address the postmarket surveillance question	A letter disapproving your plan and identifying the reasons for disapproval	Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit

§ 822.20 What are the consequences if I fail to submit a postmarket surveillance plan, my plan is disapproved and I fail to submit a new plan, or I fail to conduct surveillance in accordance with my approved plan?

The failure to have an approved postmarket surveillance plan or failure to conduct postmarket surveillance in accordance with the approved plan constitutes failure to comply with section 522 of the act. Your failure would be a prohibited act under section 301(q)(1)(C) of the act, and your device would be misbranded under section 502(t)(3) of the act. We have the authority to initiate actions against products that are adulterated or misbranded, and against persons who commit prohibited acts. Adulterated or misbranded devices can be seized. Persons who commit prohibited acts can be enjoined from committing such acts, required to pay civil money penalties, or prosecuted.

§ 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?

You must receive our approval in writing before making changes in your plan that will affect the nature or validity of the data collected in accordance with the plan. To obtain our approval, you must submit three copies of the request to make the proposed change and revised postmarket surveillance plan to the applicable address listed in § 822.8. You may reference information already submitted in accordance with § 822.14. In your cover letter, you must identify your submission as a supplement and cite the unique document number that we assigned in our acknowledgment letter for your original submission, specifically identify the changes to the plan, and identify the reasons and justification for making the changes. You must report